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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,657	01/24/2001	Francisco Cabrera	Mo-6151/MD-96-6	3791

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EXAMINER
SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,657	CABRERA, FRANCISCO	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2003 (paper no.8)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (3 months), the Request for Continued Examination (RCE), the Associate Power of Attorney letter and the Amendment, all filed 03/13/03 is acknowledged.

Claims 1-8 are pending. Claims 1, 2, 6 and 8 have been amended. Claims 1-8 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vetter *et al.* (US Pat. No. 5, 808,076).

Vetter et al. disclose solid oral preparations of micronized quinolone- or naphthyridonecarboxylic acids for use in feed formulations that mask bitter flavoring and fight bacterial infections in humans and animals (see reference column 1, lines 1-45); (column 2, lines 44-58); (column 3, lines 50-65); (column 5, lines 19-35) and claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vetter et al. (US Pat. No. 5,808,076).

As discussed above, Vetter teaches solid oral preparations of quinolone- or naphthyridonecarboxylic acids wherein the particles may be micronized form and are used in feed formulations that mask bitter flavoring and fight bacterial infections in humans and animals (see reference column 1, lines 1-45); (column 2, lines 44-58); (column 3, lines 50-65); (column 5, lines 19-35) and claims. The preparation also contains polyvinyl alcohols, polyethylene glycols and the like (col. 2, lines 49-58).

The instant claims are drawn to a solid phase dispersion comprising micronized quinolonecarboxylic acid or micronized naphthyridonecarboxylic acids in an insoluble matrix.

Vetter teaches at col. 3, lines 63-65, that if small particles are required, micronizing may be an option, for example by using an air impact, bead or trituration mill. Vetter also teaches sieving, grinding and granulation of particles at col. 3, lines 57-62. This meets the requirements of the instant generic claims, which require micronized quinolonecarboxylic acid or micronized naphthyridonecarboxylic acids, since Vetter teaches the option of micronizing to obtain smaller-sized particles. Furthermore, it would have been obvious to one of ordinary skill in the pharmaceutical art to conduct micronization of particles, if smaller particle sizes were desired, as this is routinely or conventionally practiced in the art.

Claims 1-2 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange et al. (US Pat. No. 5,152,986) in view of Vetter et al. (US Pat. No. 5,808,876).

Lange teaches a solid oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use in feed formulations, which mask bitter taste, improve the animal's intake and consumption of the feed formulation and fight bacterial infections in humans and animals (see reference column1, lines 1-11); (column 2, lines 48-66); (column 3, lines 36-47);

(column 5, lines 10-32); (column 6, lines 19-26, 52-66); (column 11, lines 21-52); (column 12, lines 1-31).

Lange are deficient only in the sense that he does not explicitly teach micronized quinolone- or micronized naphthyridonecarboxylic acids.

Vetter teaches solid oral preparations of quinolone- or naphthyridonecarboxylic acids wherein the particles may be micronized form if small particles are required, for example by using an air impact, bead or trituration mill (col. 3, lines 63-65). Vetter also teaches sieving, grinding and granulation of particles at col. 3, lines 57-62.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the micronized quinolone- or micronized naphthyridonecarboxylic acids of Vetter within the solid preparation of Lange because Vetter teaches that micronizing may be an option if smaller particles are desired and similarly Lange teaches quinolone- or naphthyridonecarboxylic acids wherein as demonstrated in Example 7, the active substances are *comminuted* through a grater, dried and then sieved to the *desired particle size* (see col. 8, lines 11-27). The expected result would be an improved, micronized quinolone- or micronized naphthyridonecarboxylic acids solid formulation for use in animal feed.

Claims 3-5 are reject d under 35 U.S.C. 103(a) as being unpatentable over Lange et al. (US Pat. No. 5,152,986) *or* Vetter et al. (US Pat. No. 5,808,876) in view of Pollinger *et al.* (US Pat. No. 5,695,784).

As discussed above, *Lange* teaches a solid oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use in feed formulations, which mask bitter taste, improve the animal's intake and consumption of the feed formulation and fight bacterial infections in humans and animals (see reference column1, lines 1-11); (column 2, lines 48-66); (column 3, lines 36-47); (column 5, lines 10-32); (column 6, lines 19-26, 52-66); (column 11, lines 21-52); (column 12, lines 1-31).

Vetter teaches a solid, homogeneously dispersed oral preparation comprising micronized quinolone- or micronized naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use with taste-sensitive animals for the treatment of bacterial infections (see reference column 1, lines 1-45); (column 2, lines 44-58); (column 3, lines 50-65); (column 5, lines 19-35); and claims.

Lange or Vetter are lacking only in the teachings of shellac in the quinolonecarboxylic acid formulation. It is well within the skill of the pharmaceutical art that various binders and film-forming agents can be implemented, in combination, to

increase the mechanical stability and strength of oral preparations. Such skill is also evident from the reference of Pollinger et al. (see below).

Pollinger teaches flavor-masked pharmaceutical compositions comprising naphthyridone- and quinolone-carboxylic acid in combination with shellac, polyethylene glycol and polyvinyl alcohol for example (see reference column 1, lines 30-67); (column 4, lines 9-59); (column 5, lines 7-15, 45-53).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use shellac in combination with quinolone- or naphthyridonecarboxylic acids to mask ill-flavored compositions in feed or foodstuff applications because Pollinger teaches shellac as a suitable ingredient in the naphthyridone- and quinolone-carboxylic acid formulation and similarly, Lange and Vetter teach naphthyridone- and quinolone-carboxylic acid preparations for use in animal feed to mask ill-flavored tastes. The expected result would be an improved tasting, therapeutic composition for the treatment of bacterial infections in humans and animals.

Lange or Vetter do not teach the instantly claimed ratios. However, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art that suitable ranges could be obtained through routine or manipulative experimentation, as these are viewed as variable parameters, in order to obtain the best possible results.

Response to Arguments

Applicant's arguments filed 03/13/03 have been fully considered and were found to be persuasive with regards to the 35 USC 102(b) rejections over Lange et al.

The applicant argued in regards to the 35 USC 102(b) rejections of Lange, stating, "Lange et al. disclose ion exchange resins which are loaded with quinolonecarboxylic acid derivatives. However, Lange et al. does not disclose *micronized* quinolonecarboxylic acid nor *micronized* naphthyridonecarboxylic acid. Furthermore, Lange does not disclose a method of preparing a solid dispersion by forming a hydrate of micronized quinolonecarboxylic acid or micronized naphthyridonecarboxylic acid.

This argument was found to be persuasive and as such, the 35 U.S.C. 102(b) rejections over Lange have been withdrawn.

Secondly, the applicant argued regarding the 35 U.S.C. 102(b) rejections of Vetter et al., stating, "Vetter et al. discloses preparation of a formulation of quinolonecarboxylic acid or naphthyridonecarboxylic acid and embonic acid. However, Vetter does not teach or disclose *micronized* quinolonecarboxylic acid nor *micronized* naphthyridonecarboxylic acid. Furthermore, Vetter does not disclose a method of preparing a solid dispersion by forming a hydrate of micronized quinolonecarboxylic acid or micronized naphthyridonecarboxylic acid.

This argument has been fully considered, but was not found to be persuasive. Vetter discloses a solid oral preparation comprising quinolone- or naphthyridonecarboxylic acids for use in feed formulations, which mask bitter flavoring and fight bacterial infections in humans and animals. Additionally, Vetter discloses at column 3, lines 63-65, that if particularly small particles are required, micronizing may be an option, for example by using an air impact, bead or trituration mill. Vetter also discloses at col. 3, lines 57-62, that the formulation is sieved, ground, and granulated, which are suitable methods for preparation. As such, Vetter recognizes that the particle formulations of quinolonecarboxylic acid or naphthyridonecarboxylic acid can be in a micronized form and therefore the instant claims are anticipated by the prior art of Vetter.

Lastly, the applicant argued regarding the 35 U.S.C. 103(a) rejections of Lange et al. or Vetter et al. in view of Pollinger et al., stating, "The deficiencies of Lange and Vetter are not remedied by Pollinger et al. Pollinger does not teach or suggest micronized quinolonecarboxylic acid or micronized naphthyridonecarboxylic acid. One skilled in the art would not have been motivated to use micronized quinolonecarboxylic acid or micronized naphthyridonecarboxylic acid to mask ill-flavored compositions with the expected result of obtaining improved tasting therapeutic compositions."

This argument has been fully considered, but was not found to be persuasive. The prior art teaches formulations comprising quinolonecarboxylic acid or naphthyridonecarboxylic acid. Moreover, Vetter et al. discloses a preparation

comprising quinolone- or naphthyridonecarboxylic acids, wherein if smaller particles are desired, the particles can be in micronized form. Similarly Lange teaches solid preparations containing quinolonecarboxylic acid for use in feedstuffs, as similarly desired by the applicant. Pollinger et al. was relied upon for the generic teaching of the use of shellacs in flavor-masking compositions containing quinolonecarboxylic acid or napthyridonecarboxylic acid and therefore resolves the only deficiency in Lange or Vetter. As such, the instant claims are rendered obvious and unpatentable over the prior art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
May 19, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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